REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS & AMENDMENTS

As correctly stated in the Office Action Summary, claims 1-3, 5-8, 10-12, and 14-18 were pending in this application when last examined. These claims have been examined on the merits, and stand rejected.

The present amendment amends claims 1,6, 14, 15, and 17.

Claims 1-3, 5-8, 10-12, and 14-18 are pending in this application.

Support for the amendments to claims 1, 6, 14, 15, and 17 regarding the S/M binding can be found in the Specification, for example, at page 14, lines 11-17.

Therefore, no new matter has been added by this amendment.

II. REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-3, 5-8, 10-12, and 14-18 are newly rejected under 35 U.S.C. § 112, second paragraph as purportedly being indefinite for failing to particularly point out the subject matter of claims. See Office Action, page 3. Applicants respectfully traverse this rejection as applied to the amended claims and for the following reasons.

Regarding the acronym "S/M", Applicants have amended the claims such that this acronym is spelled out when used for the first time in each independent claim. Support for the language defining S/M can be found in the Specification, for example, at page14, lines 11-17.

The Examiner contends that claim 16 conflicts with claim 15, because the detection antibody in claim 15 is an anti-*S. Sobrinus* antibody whose S/M binding selectivity is not less than 100, and purportedly excludes the anti-*S. mutans* antibody of claim 16. However, claim 15 recites that the detection antibody "comprises" the anti-*S. sobrinus* antibody having an S/M binding selectivity of not less than 100. Accordingly, the open language of this claim includes a second antibody that binds to *S. mutans*.

III. REJECTIONS UNDER 35 U.S.C. § 103

A. Babaahmady, Cabilly

Claims 1-3, 5-8, 10-12, 14, 17, and 18 are rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Babaahmady et al., CARIES RESEARCH, Vol. 32, pp. 99-104 (1998), in view of Cabilly et al., U.S. Pat. No. 4,816,567. See Office Action, pages 4-6.

Applicants respectfully traverse this rejection for the following reasons.

The claims call for a method for detecting *Streptococcus sobrinus* in a test fluid utilizing an anti-*S. sobrinus* antibody whose S/M binding selectivity is not less than 100 wherein S/M binding selectivity is defined as a ratio of the quantity of *Streptococcus sobrinus* to that of *Streptococcus mutans* when the antibody has reacted with *Streptococcus sobrinus* and with *Streptococcus mutans* to give an identical reaction value. Babaahmady and Cabilly fail to render the claimed invention obvious because they fail to teach and/or suggest this detection antibody.

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. Third, the prior art must provide a reasonable expectation of success.

In this case, Babaahmady and Cabilly fail to render the claimed invention obvious because they fail to teach and/or suggest each and every element of the claimed invention, namely, the detection antibody. As indicated by the Examiner at page 5, lines 1-2 of the Office Action, the primary reference of Babaahmady does not teach making the anti-*S. sobrinus* antibody having a higher binding specificity. Nor does Babaahmady teach an anti-*S. sobrinus* antibody whose S/M binding selectivity is not less than 100 as claimed.

Instead, the Examiner relies on the newly cited reference of Cabilly as allegedly teaching that it would have been obvious to modify the antibody in Babaahmady to arrive at Applicants' novel antibody in accordance with the claimed invention. In this regard, the Examiner at page 5, lines 3-12 of the Office Action asserts that Cabilly teaches:

(i) binding specificities are highly refined and can result in multitude of specificity capabilities being remarkably complex and variable;
(ii) antibodies are the foundation of immuno-diagnostic test for many antigenic substances;
(iii) altered antibodies techniques are taught as mechanism to create redesigned antibodies with desired characteristics;
(iv) changes in the variable region will improve binding specificity; and
(v) genetic manipulation techniques are taught as ways to improve specificity to particular surfaces or allow selective segregation of an antibody.

From this, the Examiner believes that Cabilly teaches a variety of ways to improve antibody selectivity. However, Cabilly also teaches the following:

> Fifth, and perhaps most important, production by current techniques (either by hybridoma or by B cell response) does not permit manipulation of the genome so as to produce antibodies with more effective design components than those normally elicited in response to antigens from the mature B cell in situ.

Cabilly, col. 2, lines 59-65. Thus, Cabilly suggests that genetic manipulation techniques are essential to create redesigned antibodies with desired characteristics.

However, with regard to antibodies which are created by genetic manipulation techniques, Cabilly (col. 27, line 29- col. 28, line 15) concretely refers only to the construction of "an expression vector for a chimeric heavy (gamma) chain which comprises the murine anti CEA variable region and human γ-2 constant region. In this regard, Cabilly states that "the resulting protein from expression will contain variable region from murine anti CEA antibody and constant region from the human γ-2 chain." Cabilly, col. 27, line 29- col. 28, line 15, (emphasis added). Moreover, as pointed out by the Examiner, at col. 7, lines 32-34, Cabilly states that "[c]hanges in the variable region will be made in order to improve the antigen binding characteristics."

Cabilly is not enabling for making such an antibody. Cabilly provides no guidance as to what kind of antigen binding characteristics are brought about by making such changes, nor the manner of making such changes, nor to what extent, the changes are made to amino acids of the variable region. Besides, Cabilly (col. 19, lines 60-63) further teaches that "mature unglycosylated protein (MW 24,553) has a variable region of 119 amino acids, including the J1

joining region of 12 amino acids..." Yet, Cabilly provides no enabling disclosure as to which of the more than 100 amino acids needs to be altered so as to obtain the desired antibody with requisite antibody specificity.

Furthermore, Cabilly lacks a reasonable expectation of successfully arriving at the desired antibody. In this regard, when each one of amino acids is to be changed, the number of variant antibodies becomes 20^{100} since there are 20 kinds of amino acids. It would be nearly impossible to select a desired the antibody from said 20^{100} antibodies.

The antibody of the present invention, on the other hand, can be obtained through an absorption treatment using cells of *Streptococcus mutans* added at a high proportion of not less than 40 (OD_{600}) to 1 mg of the raw antibody. See the specification, at page 24, line 26 to page 25, line 7. Therefore, the present invention and the *anti-S. sobrinus* antibody *per se* whose S/M binding selectivity is not less than 100 which is used in the present invention is unobvious over Babaahmady in view of Cabilly.

Thus, in view of the above, the claimed invention is not obvious over the cited references because the cited art references fail to teach each and every element of the claimed invention, and they lack a suggestion to combine/modify the reference teachings to arrive at the claimed invention. Therefore, in view of the foregoing amendments and remarks, the rejection of claims 1-3, 5-8, 10-12, 14, 17, and 18 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

B. Sommer, Babaahmady & Cabilly

Claims 15 and 16 are newly rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Sommer, U.S. Pat. No. 5,569,608, in view of Babaahmady and Cabilly. See Office Action, pages 6-7.

Applicants respectfully traverse this rejection for the same reasons given immediately above and for the following reasons.

Applicants herein reiterate the arguments set forth above with regard to Babaahmady and Cabilly. In this regard, as set forth above, Babaahmady and Cabilly fail to teach the desired antibody.

Sommer fails to remedy this deficiency. Instead, according to the Examiner, Sommer teaches immunochromatographic strips which are popular since they apply visual detection schemes (Sommer, col. 1, lines 5-9). However, Sommer neither mentions nor suggests the detection antibody which is used in claimed invention. As discussed above, the use of said detection antibody would have been unobvious over Babaahmady and Cabilly. Thus, since neither Sommer, Babaahmady nor Cabilly teach the desired antibody, these references cannot render obvious the claimed invention. Therefore, the rejection of claims 15 and 16 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the present application is in condition for allowance and notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below to expedite prosecution of the present application.

Respectfully submitted,

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THE COMMISSIONER IS AUTHORIZED TO CHARGE ANY DEFICIENCY IN THE FEES FOR THIS PAPER TO DEPOSIT ACCOUNT NO. 23-0975

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